Development and Optimisation of a Sustainable Standard Operating Protocol for Medical Nutrition Therapy to Improve Maternal and Foetal Outcomes among Gestational Diabetes Mellitus Women

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1. Title

Development and Optimisation of a Sustainable Standard Operating Protocol for Medical Nutrition Therapy to Improve Maternal and Foetal Outcomes among Gestational Diabetes Mellitus Women

2. Introduction

Gestational Diabetes Mellitus (GDM) is one of the most common disorders of pregnancy and its increasing incidence in women of all ethnicities and social strata is a cause of concern. Gestational Diabetes Mellitus is defined as any glucose intolerance with first onset or first recognition during pregnancy.

Globally, as reported by the International Diabetes Federation (IDF) Atlas 2021, 21.1 million (16.7%) of live births to women had some form of hyperglycaemia in pregnancy with 80.3 per cent being due to GDM, 10.6 per cent as a result of diabetes detected prior to pregnancy and 9.1 per cent due to Type1 and Type 2 Diabetes Mellitus first detected during pregnancy pointing out that the fact that diabetes is becoming a complication of pregnancy. The prevalence of GDM in India ranges from 3.8 to 21 per cent in different regions. Compared to rural areas, GDM is more common in cities (Seshiah *et al.,* 2009) and an exponential increase in the rate of gestational diabetes mellitus is seen which has escalated from 4 to 6 per cent in the early 90's to 16 to 20 per cent of all pregnancies (Savitha and Mageshwari, 2013). According to Manju and Abin (2015) and Paulose (2008), the prevalence of GDM was found to be 15.9 per cent in northern Kerala and 11.2 per cent in southern Kerala.

GDM is a growing maternal health burden not only because of the negative implications on the health of the mother during the gestation and perinatal period but also of the potentially lifelong consequences it may have on the mother and child. It is a known fact that GDM increases the risk of type 2 diabetes mellitus later in life for both the mother and child, along with all the other future risks and complications of cardiovascular, renal problems that come along with it. Hence, it is necessary to screen, diagnose and treat hyperglycemia in pregnancy with the involvement of a multidisciplinary team for GDM management. According to Kintiraki and Goulis (2018) a multidisciplinary treatment approach which includes lifestyle modifications, medical nutrition therapy, adequate physical activity and pharmacological intervention are the best approaches in GDM management. Harthi et.al (2022) showed that implementing a structured comprehensive multidisciplinary team in the management of diabetes in pregnancy has a positive impact on improving the maternal and fetal outcomes.

Medical Nutrition Therapy is the cornerstone of GDM management and following the Nutrition Care Process (NCP) based on nutrition assessment, nutrition diagnosis, nutrition intervention, nutrition monitoring and evaluation is crucial for effective nutritional management of GDM. According to Duarte-Gardea et al. (2018), the recent guidelines for GDM by Academy of Nutrition and Dietetics, focusing on individualised MNT based on NCP is helpful for GDM women for effective blood glucose control as well as attain proper weight gain while providing essential macro and micronutrients.

Several national and international guidelines have been put forward over the years for the diagnosis and management of GDM. However, there are still differences in the ideal time for screening, optimal cut off points for diagnosis and the methods of treatment to be carried out for GDM. The World Health Organisation WHO (1999), Diabetes in Pregnancy Study Group India (DIPSI), American Diabetes Association (ADA) and International Association of Diabetes and Pregnancy Study Groups (IADPSG) recommendations are the commonly used methods for screening and diagnosis of GDM. In India, the national guidelines for GDM management developed by Maternal Health Division came into existence in 2014 which was further revised in 2018.

It is thus clear that timely screening and adequate treatment of GDM can minimize the impact on adverse consequences. When GDM is diagnosed early, evidence-based lifestyle interventions can reduce the risk of developing Type 2 Diabetes Mellitus in both the mother and baby in the future (Sahu et,al,2021).

3. Definition of the problem

The increasing prevalence of GDM has been concomitant with the inconsistencies in the existing GDM treatment strategies and provision of a protocol based individualized medical nutrition therapy based on nutrition care process becomes very crucial in this context. This research gap identified the need to study the existing practices and also develop a sustainable standard operating protocol for MNT, validate and implement it so as to reduce adverse maternal and foetal outcomes thereby preventing diabetes mellitus among women as well as future generation.

With this in mind, a study was conducted with the following objectives and hypotheses.

4. 1.Primary Objective

- To develop and optimise a Sustainable Standard Operating Protocol (SSOP) for Medical Nutrition Therapy (MNT) for Gestational Diabetes Mellitus (GDM) women
- To determine the outcomes of implementation of the SSOP on GDM women

4.2. Secondary Objective

- To assess the current practices /protocols for GDM management followed in selected hospitals
- To identify the lacunae in MNT for GDM women
- To develop, validate and optimise a SSOP for MNT of GDM

4.3.1. Hypothesis 1

- There is no difference in the current GDM management practices in hospitals based on national guidelines for GDM

4.3.2Hypothesis 2

- There is no difference in maternal and foetal outcomes with a protocol-based MNT for GDM management

4.4. Scope

- Evidence-based protocols for GDM management would aid in early identification and management of GDM, thereby contributing to wholesome healthcare for women.
- Economical burden of GDM in the family and the healthcare system can be minimized.
- Long term consequences of GDM both in the mother and her offspring can be effectively reduced leading to improved maternal and child health outcomes and a sustainable healthcare system.

5. Methodology

The methodology was carried in four phases as follows.

5.1. Phase I: Study the Current Practices in the Treatment of GDM

5.2. Phase II: Augment, Validate and Optimise a Sustainable Standard Operating Protocol (SSOP) for Medical Nutrition Therapy (MNT) of GDM women

5.3. Phase III: Develop, Validate and Optimise a Mobile App for SSOP

5.4. Phase IV: Implement and Evaluate the SSOP on Maternal and Foetal outcomes

5.1. Phase I: Study the Current Practices in the Treatment of GDM

5.1.1. Ethical Approval

The research study was approved by the following institutions.

- Institutional Human Ethical Committee of Avinashilingam Institute for Home Science and Higher Education for Women, Coimbatore, Certificate no: AUW/IHEC/FSMD-19-20/XPD-26.
- Aster Medicity, Kochi, Kerala, Certificate no: AM/EC/99-2019 (Annexure 2a)
- Amrita Institute of Medical Sciences, Kochi, Kerala, Certificate no: IRM-AIMS-2019-079 (Annexure 2b).

The study was carried out in four multispecialty hospitals and three maternity hospitals in Kochi, Kerala through purposive sampling to understand the current practices followed in the management of GDM. The medical team for GDM management comprised of physicians namely obstetricians, diabetologists and neonatologists followed by the paramedical team namely nurses, dietitians, diabetes educators, physiotherapists, psychologists and biochemists and lastly the administrative side for maintaining quality through protocols, the quality control managers. Hence the entire medical teams in all the selected hospitals were taken through purposive sampling criterion. A total of 200 healthcare professionals involved in the management of GDM were selected.

Pregnant women both GDM and Non-GDM are the end users in the maternal health care system. Hence, pregnant women were identified in order to have a wholesome picture of the efficacy of management protocols. A total of 160 pregnant women attending the outpatient unit of the department of obstetrics and gynaecology of the selected hospitals were recruited into the study following the inclusion and exclusion criteria.

a. Inclusion Criteria

- Both GDM and Non-GDM women
- Willingness to participate
- Age group 18-45 years
- Singleton pregnancy
- Viable pregnancy (after ultrasound guided confirmation)

b. Exclusion Criteria

- Pre-gestational diabetics
- Multifoetal pregnancy
- Severe Infections (Herpes Zoster)
- Comorbidities (gestational hypertension, epilepsy, severe anaemia, thalasemia)

A bilingual informed consent was taken from all the pregnant women who participated in the study. A questionnaire was framed to elicit details on demographic details and the existing practices in GDM management from the healthcare professionals by integrating the components given in the guidelines of

(i) Women in India with Gestational Diabetes Mellitus Strategy (WINGS-5) study (Mahalakshmi et.al 2016)

(ii) Gestational Diabetes Dietetic Practice Survey (Morrison et al. 2011) and

(iii) Diagnosis and Management of Gestational Diabetes Mellitus: Technical and Operating Guidelines (Ministry of Health and Family Welfare, Government of India, 2018).

In addition to the relevant components, practices and protocols pertaining to nutrition care process were added and was pilot tested among 10 medical and paramedical professionals from the target group. Suggestions and validation was done by the HCPs and it was incorporated into the final questionnaire.

An interview schedule was framed to obtain demographic details, anthropometric measurements, biochemical investigations, clinical data pertaining to ultrasound scans, medical and obstetric history, nutrition and lifestyle patterns, treatment received, delivery details, maternal and foetal outcomes using the management guidelines given in

i. Women in India with Gestational Diabetes Mellitus Strategy (WINGS-5) study (Mahalakshmi et.al 2016) and
ii. Gestational Diabetes Questionnaire, Foetal Diagnostic Institute of the Pacific, Honolulu, Hawai, 2014

The perception of pregnant women towards managing pregnancy was assessed using a score card (given in Gestational Diabetes Questionnaire, Foetal Diagnostic Institute of the Pacific, Hawai,2014) with scores ranging from 0 to 10, where '0' represented the least score and '10' represented the highest score. The entire patient care services for pregnant women including patient education activities were also elicited from the interview schedule. The patient education activities were collected through non-participant observation method.

5.1.2. Gap Analysis of Existing Practices/Protocols in GDM Management

Gap analysis is either a tool or a process to identify where gaps are and what differences exist between an organization's current situation and "what ought to be" in place (Kim et al., 2018). The gap analysis of the existing practices/protocols in the hospitals was performed to identify the gaps in medical management practices as well as MNT practices in GDM and reason out the cause of their occurrence.

5.2. Phase II - Augment, Validate and Optimise a Sustainable Standard Operating Protocol (SSOP) for Medical Nutrition Therapy (MNT) of GDM women

5.2.1. Augmentation of SSOP

The lacunae observed in the existing SOPs showed that MNT practices followed were not optimum and thus the setting up of a Standard Operating Protocol (SOP) to facilitate consistency and improvement in MNT practices was found to be essential.

A Standard Operating Procedure (SOP) is defined as a set of written instructions that document a routine or repetitive activity followed by an orgnisation (United States Environmental Protective Agency, 2007). In the present study, the SOP is termed as Sustainable Standard Operating Protocol (SSOP) with the aim that such a SOP for MNT practices for vulnerable groups like GDM women in particular would ultimately lead to sustainable nutrition defined by Guillaumie et.al, 2020 as "a field of study and practice on the processes used to feed oneself sustainably." The SSOP based MNT comprising guidelines for screening, nutrition assessment, nutrition intervention, nutrition monitoring and evaluation was prepared based on

i. Diagnosis and Management of Gestational Diabetes Mellitus: Technical and Operating Guidelines, Ministry of Health and Family Welfare, Government of India, 2018.
ii. GDM guidelines, Academy of Nutrition and Dietetics, 2016.
iii. Gestational weight recommendations, Institute of Medicine and National Council Report, 2009.
iv. Recommended Dietary Allowances ICMR-NIN, 2020.
v. "Am I at risk for gestational diabetes?" of *Eunice Kennedy Shriver* National Institute of Child Health and Human Development, US Department of Health and Human Services, National Institutes of Health, 2012.

The initial step in SSOP is GDM risk screening which aims to identify pregnant women at risk of developing GDM. The GDM risk screening process would be used to identify pregnant women, who are at GDM High Risk, GDM Average Risk and GDM Low Risk.

Nutrition Assessment is the next step in the SSOP, which involves collecting and assessing anthropometric details, relevant biochemical investigations, clinical data, nutrition and lifestyle patterns of pregnant women, previous medical and obstetric history.

Nutrition Diagnosis is the third step in the SSOP, which a statement is written based on the nutrition assessment of the pregnant women. The nutrition diagnosis is written in a format called the "Problem-Etiology-Signs and Symptoms (PESS)" statement, which

describes the patient's nutritional problem, the related factors contributing to the nutritional problem and the specific characteristics of the nutritional problem.

Nutrition Intervention is the next step in the SSOP, which were based on the severity of the GDM risk assessed among screened pregnant women. Nutrition intervention encompassed prescription of diet plan, diet counselling and nutrition education through webinars, group contact and providing e-booklet on lactation and complementary feeding after delivery which are described as follows.

(i) GDM High Risk women

- A customized diet plan based on pre-pegnancy BMI, ideal body weight and expected gestational weight gain and diet counselling at first antenatal visit followed with monthly diet counselling of 20 minutes duration.
- Physical activity in the form of walking for 30 minutes three to five times per week also would be included based on patient's fitness evaluated by the treating doctor.
- Further nutrition education in form of webinars of 1 hour duration on topics such as nutrition in pregnancy, nutrient adequacy of diets, importance of gestational weight gain and physical activity, healthy recipe videos through group contact using social media and provision of e-booklet after delivery.

(ii) GDM Average Risk women

- Diet counselling of 20 minutes duration once every trimester without a customised diet plan.
- Nutrition education in form of webinars with one hour duration on topics such as nutrition in pregnancy, nutrient adequacy of diets, importance of gestational weight gain and physical activity through group contact using social media and provision of e-booklet after delivery.

(iii) GDM Low Risk women

- Diet counselling of 20 minutes duration at first antenatal visit only without a customised diet plan.
- Nutrition education in form of webinars of 1 hour duration on topics such as nutrition in pregnancy, nutrient adequacy of diets, importance of gestational weight gain and physical activity would also be provided through group contact using social media and provision of e-booklet after delivery.

Nutrition monitoring and evaluation is the last step in the SSOP. Nutrition monitoring involves monitoring of anthropometric details, biochemical investigations, clinical data, and

nutrition reviews. Nutrition monitoring for GDM high risk women would be conducted every month for all the described parameters as well as for clarifying diet-related queries and for dissemination of dietary guidelines and need for monitoring gestational weight gain as reminders through group contacts. GDM average risk women would undergo nutrition monitoring once every trimester for clarifying diet-related queries and for dissemination of dietary guidelines and the need for monitoring gestational weight gain. No nutrition reviews would be planned for GDM low risk women.

Nutrition evaluation consisted of the evaluation of maternal and foetal outcomes among pregnant women, impact of nutrition education, adequacy of total gestational weight gain at delivery, detection of GDM among participants and effect of SSOP on maternal and foetal outcomes which would be done for all GDM risk groups.

5.2.2. Validation of SSOP

Content validation of the SSOP was done using the Content Validity Index (CVI) calculation described by Yusoff, M.S.B, 2019. The CVI assessed relevance and representativeness of each item to a specific domain by a panel of experts. The content validation was done by a total of ten medical and paramedical team comprising two obstetricians, three diabetologists and five dietitians through as Google form questionnaire where the panelists' rate each item on the questionnaire based on a Likert scale ranging from 0 (not relevant) to 4 (highly relevant).

The CVI is calculated based on item-level content validity index (I-CVI) which is the propotion of experts giving items a relevance rating of 3 or 4 and scale-level content validity index (S-CVI) which is the average of I-CVI scores for all items on the scale or average of proportion relevance judged by all experts. The accepted CVI value for ten experts was 0.78 as described by Lynn et. al (1986) for the satisfactory level of content validity.

5.2.3. Optimisation of SSOP

The optimisation of the SSOP based MNT was done among 10 pregnant women throughout their gestation period so as to make the SSOP optimum for use. This involved conducting screening, nutrition assessment, nutrition diagnosis, nutrition monitoring and evaluation from first trimester till delivery.

5.3. Phase III -Develop, Validate and Optimise a Mobile App for SSOP

5.3.1. Development of a mobile App for the SSOP

Deriving the diet prescription based on the SSOP based MNT plan was found to be time consuming by the investigator as it involved a lot of manual calculations. The need for

simplifying the SSOP based MNT plan was thus greatly felt**.** Use of technology for faster and more accurate access to quality patient care and treatment is the need of the hour. Hence, development of mobile App for the SSOP based MNT was decided. The contents of the mobile App was developed based on the SSOP with the aim to easily conduct all the MNT processes in the SSOP namely GDM risk screening, nutrition assessment, nutrition diagnosis, nutrition intervention, nutrition monitoring and nutrition evaluation.

The App for this study was developed using the Integrated Development Environment, Android Studio which can work in both mobile and tablets with an Android Operating System. The programming language used for the App development was Kotlin. The back end to store all patient details was developed using a programming language called PHP. All the storage of information/data was done using MYSQL database. The communication between the mobile/Android App with the back end server was established using Application Programming Interface (API). The App was hosted with a popular domain register called GoDaddy with domain name www.gmoms.com described by Lynn et. al (1986) for the satisfactory level of content validity.

The database and domain for the App was taken up for rental for a period of one year as the App has been created only for the study purpose and not to be launched for commercial production purpose. The User Interface or UI for the App was developed taking into consideration of such similar existing applications. Designing of the user interface in terms of the colour, font style, logo, descriptions for template, use of radio buttons, scroll down features etc. were extensively worked on before finalising on the current design. Once the prototype of the App was ready, the researcher and the software developer tested the App extensively and all bugs were fixed.

5.3.2. Validation of the Mobile App

A Google questionnaire was prepared for content validation of the App and a panel of ten medical and paramedical staff comprising two obstetricians three diabetologists and five dietitians rated each item on a Google form questionnaire based on a Likert scale ranging from 0 (not relevant) to 4 (highly relevant). Content Validity Index (CVI) calculation described above was done to validate the mobile App also.

5.3.3. Optimisation of Mobile App

The trial version of the mobile App was created and shared to 50 healthcare professionals comprising of 25 doctors and 25 dietitians for usage. The System Usability Scale (SUS) developed by Brooke (1986) was adapted into a Google questionnaire and all healthcare professionals rated the questions and the responses were analysed to estimate the

usability of the mobile App. All suggestions regarding the usability of the App were taken up and modifications done accordingly.

5.4. Phase IV - Implement and Evaluate the SSOP on Maternal and Foetal outcomes

Although the SSOP was developed for MNT of GDM women, the SSOP also took into consideration identification of pregnant women at risk of developing GDM with the intent of preventing the occurrence of GDM among such women. Hence, for Phase IV of the study a new target group of pregnant women was selected and the SSOP implemented and evaluation of the SSOP on the maternal and foetal outcomes carried out. Phase IV of the study was carried out after taking due permission and consent from the management at only one multispeciality hospital located in Kochi, Kerala through convenience sampling, as the COVID-19 pandemic restricted conducting research at many hospitals. The interview schedule used in Phase I was used in Phase IV of the study to collect details such as background information, medical history, past obstetric history, nutrition and lifestyle history, anthropometric measurements, biochemical parameters, ultrasound reports, delivery details, maternal and foetal outcomes.

5.4.1. Selection of Sample size and Sampling technique

The sample size was calculated as per the GDM estimated prevalence range of 0 to 41.9 percent, reported in a systematic review and meta-analysis study conducted in India (Li et.al, 2018). Using the formula given below sample size was calculated using the upper limit of the estimated prevalence as follows.

$$\boldsymbol{n \geq \frac{Z_{1-\propto/2}{}^{2} * p * 1-p}{d^2}}$$

Let α=0.05, $Z_{1-\propto/2}$ = 1.96

Estimated prevalence of GDM, (p) =0.419

Precision (d) =6%

Substituting these values in the above formula

n ≥259.78

Therefore the minimum sample size required for this study was 260

5.4.2. Identification of target groups

Based on the sample size calculated and considering the chances of drop outs in the study, 372 pregnant women who came for antenatal checkups at the outpatient unit of the department of obstetrics and gynaecology of selected hospital were selected through purposive sampling method. The calculated sample size was attained only after four months of continuous screening of pregnant women based on the following inclusion and exclusion criteria.

a. Inclusion Criteria

- Pregnant women in their first trimester
- Willingness to participate
- Age group 18-35 years
- Singleton pregnancy
- Viable pregnancy (after ultrasound guided confirmation)

b. Exclusion Criteria

- Pre-gestational diabetics
- Infertility treatment
- Multifoetal pregnancy
- Severe Infections (Herpes Zoster)
- Comorbidities (gestational hypertension, epilepsy, severe anaemia, thalasemia)

A bilingual informed consent was taken from all the pregnant women who participated in the study.

5.4.3. Categorization of target group as experimental and control group

The selected sample of 372 pregnant women were categorized into two groups, namely experimental group and control group each comprising of 186 participants based on the participant's willingness to be part of the control group or the experimental group. Pregnant women who agreed to continue with the entire course of the study with regular nutrition reviews and to avail treatment in the selected hospital itself until delivery formed the experimental group and the others formed the control group. The pregnant women were then followed for the entire period of pregnancy from first trimester till delivery spanning from nine months to one year as delivery dates differed among the pregnant women. During the first trimester, eight pregnant women were dropped out of the experimental group due to miscarriage, abortion or did not want to continue in the study. Hence the total sample size reduced to a total of 364 pregnant women comprising 178 participants in experimental group and 186 participants in control group.

Face to face discussions and Power point presentations about the SSOP based MNT practices were done by the investigator with the medical, paramedical and administrative team of the selected hospital prior to implementation of the SSOP. Each step of SSOP based MNT such as screening and nutrition assessment, nutrition diagnosis, nutrition intervention, nutrition monitoring and nutrition evaluation were elaborated for establishing the smooth flow of operations described in the SSOP.

A knowledge aptitude practice (KAP) survey was conducted among a subset of 45 participants of the experimental group using a validated KAP questionnaire to evaluate the extensive nutrition education given to the experimental group. According to the United States Agency for International Development, 2011, a Knowledge, Attitude and Practices (KAP) survey is a quantitative method (predefined questions formatted in standardized questionnaires) that provides access to quantitative and qualitative information. Training sessions on the SSOP based MNT planning and practices for GDM were also taken by the investigator for dietitians and nutritionists who participated in the study. An e-nutrition booklet on lactation and initiation of complementary feeding was prepared and given to all the participants of the study after their delivery during the final MNT visit by the investigator.

6. Results

6.1. Salient findings of Phase 1

- Among the selected 200 healthcare professionals significant difference of 89.1 per cent dietitans, 81.4 per cent doctors and 70.7 per cent allied HCPs on the prevalence of GDM, GDM as risk factor for future Type 2 Diabetes Mellitus and achievement of normoglycaemia through MNT and exercise was seen. However, no difference in the among the three groups, was seen with 75.7 per cent doctors, 65.3 per cent allied HCPs and 63.6 per cent dietitians recommending early diagnosis and detection of GDM, evidence based treatment strategies, health and nutrition education, and regular follow up and evaluation as preventive measures for GDM.
- Perception of GDM and non-GDM women on the impact of GDM on pregnancy significantly differed with 55.7 percent GDM women having a greater understanding of the impact of GDM on pregnancy compared to 35.2 percent in non-GDM women. The readiness of both groups towards their current pregnancy as planned or unplanned did not show any significant difference with 92.6 percent Non-GDM women and 89.6 percent GDM women positively stating that their current pregnancy was planned, suggesting their readiness for motherhood

- **Gap Anaysis seen were as follows**

  Screening, assessment and diagnostic of GDM: No early screening and use of operating guidelines for GDM, assessment of BMI based on pre-pregnancy weight and gestational weight gain and timing and criteria used for diagnostic procedures of GDM.

  Intervention, monitoring and evaluation for GDM: Inconsistencies in MNT and exercise as the first line of intervention for GDM, choice of medicines, interdepartmental referrals, hyperglycaemia management of GDM women, hypoglycaemia management of offsprings, preliminary procedures for labour or delivery, routine time of delivery, OGTT monitoring after delivery, follow up and evaluation procedures after delivery

  MNT practices for GDM: Inconsistencies in pre-pregnancy BMI and gestational weight gain assessment based nutrient calculations and the use of operating guidelines for MNT planning.

  MNT practices received by GDM and Non-GDM: Significant difference seen in MNT received, time of receiving MNT and the HCP who provided the MNT, with GDM women receiving MNT at the time of detection of GDM and Non-GDM women receiving it after delivery. The duration of MNT of less than two weeks or initiation of MNT along with medicines was found in almost 50 per cent of the GDM women. The factors affecting compliance to MNT among both groups showed significant difference in the adequacy of diet quality and quantity indicating that such issues were more prominent among GDM women than their counterparts. Overall nutrient intake was found to be lower than RDA for energy, protein, calcium, iron and fibre and higher than RDA for carbohydrates and fats among both groups. The physical activity patterns with respect to type, duration and frequency of exercise did not show any significant difference between GDM and non-GDM women.

- The delivery outcomes observed showed that mode of labour, birth outcome and adverse foetal outcomes were the parameters found to be significant difference with spontaneous labour of 13.9 per cent in GDM women compared to 35.3 percent in Non-GDM women. The birth outcomes recorded were 27.8 percent preterm delivery among GDM women compared to 5.9 percent in Non-GDM women. Adverse foetal outcomes were 61.1 percent in GDM women compared to 30.2 percent in non-GDM women. These results indicated GDM women to be at greater risk for adverse maternal and foetal outcomes compared to their counterparts.

- ❖ **Hypothesis 1 is thus rejected.** There is difference in the current GDM management practices in hospitals based on national guidelines for GDM

6.2. Salient findings of Phase 2

- Based on the limitations observed in Phase I of the study, the Sustainable Standard Operating Protocol (SSOP) was developed based on the nutrition care process (nutrition assessment, diagnosis, intervention, monitoring and evaluation) for GDM.
- GDM risk screening and assessment incorporated, nutrition diagnosis included, nutrition intervention based on GDM risk assessment, pre-pregnancy BMI, gestational weight gain planned and nutrition evaluation and monitoring of outcomes assessed at delivery.
- The validation of SSOP using content validity index showed a scale-level content validity index/average (S-CVI/Ave) value of 0.99 which was greater than the accepted CVI value of 0.78 and confirmed the SSOP to achieve satisfactory level of content validity.
- Optimisation of the SSOP done by implementation of SSOP on 10 pregnant women equally grouped into experimental (N=5) and control group (N=5) showed two pregnant women from control group and three pregnant women from experimental group to be in GDM high risk category.
- Nutritional assessment: BMI (BMI>25kg/m^2) was greater in experimental group than in control group. Mean nutrient intake did not show any difference when compared among both groups.
- Nutrition diagnosis: Knowledge deficit was more among control group than experimental group.
- Nutrition intervention: Equal number of pregnant women in both experimental and control group were diagnosed with GDM. However, mean post prandial blood sugar (PPBS) was greater in the control group than the experimental group.
- Nutrition monitoring and evaluation: Maternal and foetal adverse outcomes were more in control group than experimental group.

6.3. Salient findings of Phase 3

- The developed Mobile App for SSOP consisted of a total of eight screens as follows.
- **Welcome screen**: Designed with a unique background image of a pregnant woman and depiction of the logo in the centre of the screen with a short text for user's to get an idea of the main functionality of the App.

- **Login Screen**: The user was prompted to create an acccount or sign in.
- **Add/Update/Delete Screen:** Aids the user for multiple functions like adding a patient, deleting a patient and updating the details already entered of a patient.
- **Personal Details Screen**: Collect the personal details such as name, date of birth, mobile number, email id, education, employment, activity level and hospital registration number of the patients.
- **Medical Details Screen:** Capptures anthropometric details such as height, pre-pregnancy weight, and current weight for calculating pre-pregnancy BMI and ideal body weight.
- **Laboratory Details Screen**: Relevant biochemical parameters of the patient such as haemoglobin, fasting blood glucose, post prandial blood glucose, random blood glucose, glycosylated haemoglobin, thyroid stimulating hormone, oral glucose tolerance test values, self monitoring of blood glucose values and blood pressure are captured.
- **Medicine Details Screen:** All the medications prescribed to the patient along with the dosage and time for taking those medications is captured.
- **Result Screen**: Most important screen of the App which displays the results of GDM risk assessment, BMI, expected gestation weight, total weight gain needed for the entire period of pregnancy, excess or deficit in gestational weight gain for the current period of gestation, energy and protein requirement and the percentage distribution of nutrients namely carbohydrates, proteins and fat.
- **Validation of the Android App**: Content validity index used showed a scale-level content validity index/average (S-CVI/Ave) value of 0.88 which was greater than the accepted CVI value of 0.78 and confirmed that the Android App developed achieved satisfactory level of content validity.
- **Optimisation of the Mobile App**: System Usability Scale (SUS) Grade used showed that the mean SUS score was not found to be significantly different (p=0.128) with 78.90±7.18 among doctors and 82.20±7.85 among dietitians. The mean scores calculated from both groups corresponded to an overall grade of A- and A respectively indicating that the Mobile App was highly acceptable in terms of its usability.

6.4. Salient findings of Phase 4

- **SSOP implementation:** The GDM Risk Screening conducted among the selected 178 pregnant women in experimental group and 186 pregnant women control group did

not show marked difference suggesting the homogeneity in the distribution of GDM high risk, average risk and low risk pregnant women within the groups..

- **Nutrition Assessment:** Mean height was the only variable showing significant difference with 159.08±6.45cm in control group compared to 157.70±5.04cm in experimental group. All other anthropometric variables such as pre-pregnancy weight, body mass index did not vary between groups. The mean value of all biochemical markers namely RBS, FBS, Hb and TSH levels did not show any significant difference conveying that these were almost the same within groups. Presence of antenatal complications significantly differed within groups with no occurrence of 77.5 per cent in experimental group compared to 53.8 percent in control group. The overall nutrient intake among experimental and control group for all nutrients such as energy, protein, fat, iron, calcium and fibre were signifcantly lower than RDA except for carbohydrate which significantly exceed RDA.
- **Nutrition Diagnosis:** The nutrition diagnosis derived from both groups did not show significant difference among the target groups indicating it to be similar in both groups.
- **Nutrition Intervention**: The Knowledge Attitude Practice (KAP) pre and post test scores of participants showed significant difference indicating that the nutrition educations sessions were effective in improving their knowledge on topics such as nutrition during pregnancy, gestational weight gain, gestational diabetes mellitus and its prevention.
- **Nutrition Monitoring:** The mean PPBS of 107.56 mg/dl in the GDM women belonging to the experimental group receiving SSOP based MNT and 114.96mg/dl in the GDM women belonging to the control group on usual MNT showed significant difference indicating that the SSOP based MNT was more effective in reducing post pradial blood sugar levels than the usual MNT. Adequacy of gestational weight gain assessed showed significant difference between groups with a greater per cent of 43.8 per cent in experimental group achieving adequate GWG than 32.2 per cent in the control group. The results reveal that the SSOP based MNT was effective in achieving adequate GWG among pregnant women belonging to experimental group.
- **Nutrition Evaluation:** Delivery details observed indicated significant difference in the mode of delivery only with more number of vaginal deliveries in control group compared to experimental group indicating that SSOP based MNT did not aid in

vaginal deliveries in the experimental group. No difference in birth outcome, induction of labour, presence of low birth weight (<2.5kg) and higher birth weight (>4kg) was seen among experimental group and control group.

- **Evaluation of NCP:** OGTT results were significantly greater with 50.5 per cent pregnant women detected with GDM in control group compared to 33.7 percent in experimental group indicating that the SSOP based MNT was effective in reducing the occurrence of GDM among experimental group.
- The comparison of GDM risk screening and GDM detection among the target groups showed that there was significant reduction in GDM detection among GDM high risk (38.5 percent) and GDM average risk women (30.6 percent) belonging to the experimental group compared to their counter parts in the control group with 58.3 percent and 36.7 percent respectively also revealing the positive impact of GDM risk screening which was part of the SSOP.
- The presence of adverse foetal outcomes revealed was 50 percent in control group which was significantly higher compared to 30.3 percent in experimental group.
- The presence of maternal outcomes among control group was significantly higher at 18.9 per cent compared to 10.2 per cent in the experimental group (p=.019) indicating that the SSOP based MNT was effective in reducing the presence of adverse maternal outcomes in experimental group compared to control group**.**
- Logistic regression done for identifying the risk for adverse foetal outcomes revealed that the model was statistically significant at the χ^2 value = 17.09 and p value less than 0.01. P-value shows that only SSOP based MNT has significance in the model. The adjusted odds ratio indicated that experimental group has 0.428 times lesser chance of having adverse foetal outcome compared to control groups.
- Logistic regression done for identifying the risk for adverse maternal outcomes showed that the model was statistically significant at the χ^2 value = 27.305 and p value less than 0.001. P-value shows that shows that intervention (SSOP based MNT), previous history of PCOS and history of DM significantly affecting the outcome of having GDM. Adjusted odds ratio indicates that experimental group has 0.505 times lesser chance of having adverse maternal outcome compared to control groups. Pregnant women having history of PCOS were 1.944 times more likely to have adverse maternal outcome compared to those not having history PCOS. Also, those

having history of GDM were 3.897 times more likely to have adverse maternal outcome compared to those not having the history of GDM.

Hypothesis 2 is thus rejected.

- There is difference in maternal and foetal outcomes with a protocol-based MNT for GDM management

7. Conclusion

The study attempted to understand the current practices in the management of GDM and identify the lacunae in medical nutrition therapy practices provided to GDM women. The lacunae identified in MNT practices were taken up to develop a sustainable standard protocol (SSOP) based MNT. The GDM risk screening included as the initial step in SSOP, helped in early identification of GDM risk, recommending GDM risk screening to be taken up as an important component of initial screening of all pregnant women. The SSOP based MNT implemented in the study thus helped in effective glucose control among GDM women and better maternal and foetal outcomes among pregnant women who were given the SSOP based MNT intervention. The study findings thus provide conclusive evidence for the need for protocol based MNT management not only for GDM women for better management, but also for Non-GDM women so that early identification of GDM risk can be done and protocol based MNT intervention given, thereby improving the maternal and foetal outcomes in a larger perspective.

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1. Sindhu, S. and Mageshwari, S.U. (2022). Medical nutrition therapy in gestational diabetes mellitus: A survey among dietitians. Journal of Diabetology. 13(3), 270-276.

2. Sindhu, S. and Mageshwari, S.U. (2022).Current practices in the management of gestational diabetes: A survey among healthcare professionals. International Journal of Food and Nutritional Sciences. 11(2), 117-126.

3. Sindhu, S. and Mageshwari, S.U. (2023). A comparative study on dietary compliance and depression among GDM and non-GDM women. Dogo Rangsang Research Journal. 13(4), 48-52.